DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 14 1999

Richard Hamer Associates, Inc.
Attention: Richard A. Hamer
P.O. Box 16598
Ft. Worth, TX 76132

Docket No. 98P-0911/CP1

Dear Mr. Hamer:

This is in response to your petition filed on October 15, 1998, and your amendment dated December 4, 1998, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Methylprednisolone Tablets, Sublingual, 4 mg and 16 mg. The listed drug products to which you refer in your petition are Medrol® (Methylprednisolone) Tablets 4 mg and 16 mg, manufactured by Pharmacia and Upjohn Co.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Sections 505(j)(2)(C)(i) and (ii) of the Act such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product, or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug product; or that any drug product with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

Your request involves a change in the route of administration from that of the listed drug products (i.e., from the oral route of administration to the sublingual route of administration). The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

The Agency has determined that your proposed change in route of administration raise questions of safety and effectiveness, and has concluded that clinical trials are required for these specific drug products. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug products.

Please contact the Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products (HFD-550) for further information regarding the types of studies required at (301) 827-2040.

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If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research